PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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By _____
JoAnn Lindman

Dear Sirs:

Pursuant to 37 C.F.R. § 41.37, Appellant hereby submits this Appeal Brief in furtherance of the Notice of Appeal filed on July 8, 2010, and of the Notice of Panel Decision from Pre-Appeal Review dated mailed September 21, 2010. Appellant authorizes the fee prescribed by 37 C.F.R. § 41.20(b)(2) in the amount of $540 to be charged to Deposit Account No. 50-0413. Permission is hereby granted to charge or credit Deposit Account No. 50-0413 for any errors in fee calculation.

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A. CLAIMS 1-10, 13, 16-21, 23-29, AND 31-41 ARE PATENTABLE UNDER 35 U.S.C. 103(a) OVER HUEBSCH ET AL. (U.S. PATENT NO. 6,312,446) IN VIEW OF HART (U.S. PATENT NO. 5,846,251) AND LAFONTAINE ET AL. (U.S. PATENT NO. 5,964,782)....14

1. *All words in a claim must be considered in judging the patentability of that claim against the prior art.* 14

2. *If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious.* 28

B. CLAIM 22 IS PATENTABLE UNDER 35 U.S.C. 103(a) OVER HUEBSCH ET AL. (U.S. PATENT NO. 6,312,446) IN VIEW OF HART (U.S. PATENT NO. 5,846,251), LAFONTAINE ET AL. (U.S. PATENT NO. 5,964,782), AND LUSCOMBE (U.S. PATENT NO. 5,683,418). ..28

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I. REAL PARTY IN INTEREST

The real party in interest is the assignee of record, Boston Scientific Scimed, Inc., a corporation organized and existing under and by virtue of the laws of Minnesota, and having a business address of One Scimed Place, Maple Grove, MN 55311-1566. An assignment from the inventor, Daniel M. Lafontaine, conveying all right, title and interest in the invention to Scimed Life Systems, Inc. has been recorded at Reel 014273, Frame 0368. A subsequent change of name to Boston Scientific Scimed, Inc. has been recorded at Reel 018505, Frame 0868.

II. RELATED APPEALS AND INTERFERENCES

There are no other known appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

Claims 1-14, 16-29, and 31-41 are pending in the application of which claims 11-12 and 14 have been withdrawn. Claims 15 and 30 have been canceled from the application.

Claims 1-10, 13, 16-21, 23-29, and 31-41 stand rejected as being unpatentable under 35 U.S.C. 103(a) over Huebsch et al. (U.S. Patent No. 6,312,446) in view of Hart (U.S. Patent No. 5,846,251) and Lafontaine et al. (U.S. Patent No. 5,964,782).

Claim 22 stands rejected as being unpatentable under 35 U.S.C. 103(a) over Huebsch et al. (U.S. Patent No. 6,312,446) in view of Hart (U.S. Patent No. 5,846,251), Lafontaine et al. (U.S. Patent No. 5,964,782), and Luscombe (U.S. Patent No. 5,683,418).

Claims 1-10, 13, 16-29, and 31-41 of the application are currently being appealed.

IV. STATUS OF AMENDMENTS

No amendments subsequent the final rejection of April 13, 2010 have been presented.

V. SUMMARY OF CLAIMED SUBJECT MATTER*

The invention relates generally to a closure device for closing an opening in a body cavity such as an arteriotomy puncture. The device includes a delivery member, a closure component, and a collapse actuator to move the closure component from an extended generally conical configuration to a disc shape in which tissue engaging members disposed on a backing engage both tissue of the patient and a portion of the backing on which the tissue engaging members are disposed as illustrated in Figs. 3-5. The disc shaped collapsed closure component closes the opening in the cavity.

Turning now to independent claim 1, which is directed to a closure device for closing an opening in a body cavity, comprising: an elongate delivery member (see, for example, specification page 3, lines 16-19, page 5, line 29 to page 6, line 13, page 8, line 7 to page 9, line 2, page 10, lines 6-21, page 11, lines 4-23 and line 29 to page 12, line 26, page 13, line 9 to page 14, line 4; Figs. 2-5, 7A, 7B, 8, and 10; reference numeral 22) having a distal end and a proximal end; a closure component (see, for example, specification page 3, line 16 to page 4, line 9, page 6, lines 3-28, page 7, lines 25-29, page 9, line 14 to page 10, line 24, page 11, line 3 to page 13, line 2, page 13, lines 7-22, page 13, line 28 to page 14, line 2; Figs. 2- 10; reference numerals 28, 50, 70, 80) removably connected to the distal end of the delivery member (see, for example, specification page 3, lines 16-19, page 5, line 29 to page 6, line 13, page 8, line 7 to page 9, line 2, page 10, lines 6-21, page 11, lines 4-23 and line 29 to page 12, line 26, page 13, line 9 to page 14, line 4; Figs. 2-5, 7A, 7B, 8, and 10; reference numeral 22), the closure component (see, for example, specification page 3, line 16 to page 4, line 9, page 6, lines 3-28, page 7, lines 25-29, page 9, line 14 to page 10, line 24, page 11, line 3 to page 13,

* The references to the specification and drawings provided herein are exemplary, and are not deemed to be limiting as support may be found throughout the specification and in many of the Figures.

line 2, page 13, lines 7-22, page 13, line 28 to page 14, line 2; Figs. 2- 10; reference numerals 28, 50, 70, 80) including a collapsible backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72) movable between a non-collapsed delivery position, in which the backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72) has a generally conical shape with a center portion of the backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72) distally spaced from a periphery of the backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72), and a collapsed deployed position, in which the backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72) center portion is collapsed proximally toward the backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72) periphery to have a generally disc shape, and a plurality of fibrous tissue engaging members (see, for example, specification page 3, line 21 to page 4, line 11, page 6, lines 13-28, page 7, line 25 to page 8, line 2 and line 13 to page 13, line 19, page 14, line 9 to page 16, line 10; Figs. 2-4, 6-9 ; reference numeral 36, 56, 74) disposed on the backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18;

Figs. 2-4, 6 ; reference numeral 34, 54, 72) and oriented in a non-engaging orientation when traveling in a distal direction and in an engaging orientation when traveling in a proximal direction, the fibrous tissue engaging members (see, for example, specification page 3, line 21 to page 4, line 11, page 6, lines 13-28, page 7, line 25 to page 8, line 2 and line 13 to page 13, line 19, page 14, line 9 to page 16, line 10; Figs. 2-4, 6-9 ; reference numeral 36, 56, 74) entangling the backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72) when the backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72) is in the collapsed position; and a collapse actuator (see, for example, specification page 5, line 29 to page 6, line 10, page 8, line 11 to page 9, line 26, page 11, line 4 to page 12, line 15, page 13, lines 9-19; Figs. 2-5, 7A, 8; reference numeral 24, 30) releasably coupled to the collapsible backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72), the actuator (see, for example, specification page 5, line 29 to page 6, line 10, page 8, line 11 to page 9, line 26, page 11, line 4 to page 12, line 15, page 13, lines 9-19; Figs. 2-5, 7A, 8; reference numeral 24, 30) having a detachable distal end that is received within a distal aperture (see, for example, specification page 9, lines 23-26) in the closure component (see, for example, specification page 3, line 16 to page 4, line 9, page 6, lines 3-28, page 7, lines 25-29, page 9, line 14 to page 10, line 24, page 11, line 3 to page 13, line 2, page 13, lines 7-22, page 13, line 28 to page 14, line 2; Figs. 2- 10; reference numerals 28, 50, 70, 80) and extends distal to the distal aperture (see, for example, specification page 9, lines 23-26) when the closure component (see, for example, specification page 3, line 16 to page 4, line 9, page 6, lines 3-28, page 7, lines 25-29, page 9, line 14 to page 10, line 24, page 11, line 3 to page 13, line 2, page 13, lines 7-22, page 13, line 28 to page 14, line 2; Figs. 2-10; reference numerals 28, 50, 70, 80) is in the non-collapsed position, the collapse

actuator being operable to move the collapsible backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72) from the non-collapsed position to the collapsed position, and wherein the detachable distal end of the collapse actuator (see, for example, specification page 5, line 29 to page 6, line 10, page 8, line 11 to page 9, line 26, page 11, line 4 to page 12, line 15, page 13, lines 9-19; Figs. 2-5, 7A, 8; reference numeral 24, 30) is configured to assume a deformed profile solely in response to a sufficient proximal force applied to the collapse actuator (see, for example, specification page 5, line 29 to page 6, line 10, page 8, line 11 to page 9, line 26, page 11, line 4 to page 12, line 15, page 13, lines 9-19; Figs. 2-5, 7A, 8; reference numeral 24, 30), the deformed profile permitting the detachable distal end to pass proximally through the distal aperture (see, for example, specification page 9, lines 23-26) and thereby detach from the collapsed closure component (see, for example, specification page 3, line 16 to page 4, line 9, page 6, lines 3-28, page 7, lines 25-29, page 9, line 14 to page 10, line 24, page 11, line 3 to page 13, line 2, page 13, lines 7-22, page 13, line 28 to page 14, line 2; Figs. 2- 10; reference numerals 28, 50, 70, 80).

Turning now to independent claim 26, which is directed to a method of closing an opening in a body, comprising: inserting distally through the opening a closure component (see, for example, specification page 3, line 16 to page 4, line 9, page 6, lines 3-28, page 7, lines 25-29, page 9, line 14 to page 10, line 24, page 11, line 3 to page 13, line 2, page 13, lines 7-22, page 13, line 28 to page 14, line 2; Figs. 2- 10; reference numerals 28, 50, 70, 80) having collapsible pile backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72) with pile engaging hooks (see, for example, specification page 3, line 21 to page 4, line 11, page 6, lines 13-28, page 7, line 25 to page 8, line 2 and line 13 to page 13, line 19, page 14, line 9 to page 16, line 10; Figs. 2-4, 6-9 ; reference numeral 36, 56, 74) and tissue engaging hooks (see, for example, specification page 3, line 21 to page 4, line 11, page 6, lines 13-28, page 7, line 25 to page 8, line 2 and line 13 to page 13, line 19, page 14, line 9 to page

16, line 10; Figs. 2-4, 6-9 ; reference numeral 36, 56, 74) disposed thereon, the pile backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72) initially have a non-collapsed delivery position in which the backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72) has a generally conical shape with a center portion of the backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72) distally spaced from a periphery of the backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72); withdrawing the closure component (see, for example, specification page 3, line 16 to page 4, line 9, page 6, lines 3-28, page 7, lines 25-29, page 9, line 14 to page 10, line 24, page 11, line 3 to page 13, line 2, page 13, lines 7-22, page 13, line 28 to page 14, line 2; Figs. 2- 10; reference numerals 28, 50, 70, 80) proximally relative to the opening such that the tissue engaging hooks (see, for example, specification page 3, line 21 to page 4, line 11, page 6, lines 13-28, page 7, line 25 to page 8, line 2 and line 13 to page 13, line 19, page 14, line 9 to page 16, line 10; Figs. 2-4, 6-9 ; reference numeral 36, 56, 74) engage tissue adjacent the opening; applying proximally directed force to a collapse actuator (see, for example, specification page 5, line 29 to page 6, line 10, page 8, line 11 to page 9, line 26, page 11, line 4 to page 12, line 15, page 13, lines 9-19; Figs. 2-5, 7A, 8; reference numeral 24, 30) releasably coupled to the collapsible pile backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72) and having a detachable distal end received within a distal aperture (see, for example,

specification page 9, lines 23-26) of the collapsible pile backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72), the detachable distal end extending distal to the distal aperture (see, for example, specification page 9, lines 23-26), thereby to collapse the collapsible pile backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72) to a collapsed position in which the backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72) center portion is moved proximally toward the backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72) periphery to form a generally disc shape, and wherein the pile engaging hooks (see, for example, specification page 3, line 21 to page 4, line 11, page 6, lines 13-28, page 7, line 25 to page 8, line 2 and line 13 to page 13, line 19, page 14, line 9 to page 16, line 10; Figs. 2-4, 6-9 ; reference numeral 36, 56, 74) engage portions of the pile backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72) to retain the pile backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72) in the collapsed position; and disconnecting the collapse actuator (see, for example, specification page 5, line 29 to page 6, line 10, page 8, line 11 to page 9, line 26, page 11, line 4 to page 12, line 15, page 13, lines 9-19; Figs. 2-5, 7A, 8; reference numeral 24, 30) from the collapsible pile backing (see, for example, specification page 3, line 19 to page

4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72) by applying additional proximally directed force on the collapse actuator (see, for example, specification page 5, line 29 to page 6, line 10, page 8, line 11 to page 9, line 26, page 11, line 4 to page 12, line 15, page 13, lines 9-19; Figs. 2-5, 7A, 8; reference numeral 24, 30), thereby causing the detachable distal end of the collapse actuator (see, for example, specification page 5, line 29 to page 6, line 10, page 8, line 11 to page 9, line 26, page 11, line 4 to page 12, line 15, page 13, lines 9-19; Figs. 2-5, 7A, 8; reference numeral 24, 30) to assume a deformed profile solely in response to a sufficient proximal force applied to the collapse actuator (see, for example, specification page 5, line 29 to page 6, line 10, page 8, line 11 to page 9, line 26, page 11, line 4 to page 12, line 15, page 13, lines 9-19; Figs. 2-5, 7A, 8; reference numeral 24, 30), the deformed profile permitting the detachable distal end to pass proximally through the distal aperture (see, for example, specification page 9, lines 23-26) and the collapsed pile backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72).

Turning now to independent claim 33, which is directed to a closure device for closing an opening in a body cavity, comprising: an elongate delivery member (see, for example, specification page 3, lines 16-19, page 5, line 29 to page 6, line 13, page 8, line 7 to page 9, line 2, page 10, lines 6-21, page 11, lines 4-23 and line 29 to page 12, line 26, page 13, line 9 to page 14, line 4; Figs. 2-5, 7A, 7B, 8, and 10; reference numeral 22) having a distal end and a proximal end; an implantable closure component (see, for example, specification page 3, line 16 to page 4, line 9, page 6, lines 3-28, page 7, lines 25-29, page 9, line 14 to page 10, line 24, page 11, line 3 to page 13, line 2, page 13, lines 7-22, page 13, line 28 to page 14, line 2; Figs. 2- 10; reference numerals 28, 50, 70, 80) disconnectably connected to the distal end of the delivery member (see, for example, specification page 3, lines 16-19, page 5, line 29 to page 6, line 13, page 8, line 7 to page 9, line 2, page 10, lines 6-21, page 11, lines 4-23 and line 29 to page 12, line 26, page 13, line 9 to page 14, line 4; Figs. 2-5, 7A, 7B, 8, and 10; reference numeral 22), the closure

component (see, for example, specification page 3, line 16 to page 4, line 9, page 6, lines 3-28, page 7, lines 25-29, page 9, line 14 to page 10, line 24, page 11, line 3 to page 13, line 2, page 13, lines 7-22, page 13, line 28 to page 14, line 2; Figs. 2- 10; reference numerals 28, 50, 70, 80) including a longitudinally collapsible backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72) movable between a non-collapsed delivery position, in which the backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72) has a generally conical shape with a center portion of the backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72) distally spaced from a periphery of the backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72), and a collapsed deployed position, in which the backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72) center portion is collapsed proximally toward the backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72) periphery to have a generally disc shape, and a plurality of fibrous tissue engaging members (see, for example, specification page 3, line 21 to page 4, line 11, page 6, lines 13-28, page 7, line 25 to page 8, line 2 and line 13 to page 13, line 19, page 14, line 9 to page 16, line 10; Figs. 2-4, 6-9 ; reference numeral 36, 56, 74) on the backing (see, for example, specification page 3, line 19 to page 4, line 11, page

6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72) and engaging the backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72) when the backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72) is in the collapsed position; and a collapse actuator (see, for example, specification page 5, line 29 to page 6, line 10, page 8, line 11 to page 9, line 26, page 11, line 4 to page 12, line 15, page 13, lines 9-19; Figs. 2-5, 7A, 8; reference numeral 24, 30) releasably coupled to the collapsible backing (see, for example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72), the actuator (see, for example, specification page 5, line 29 to page 6, line 10, page 8, line 11 to page 9, line 26, page 11, line 4 to page 12, line 15, page 13, lines 9-19; Figs. 2-5, 7A, 8; reference numeral 24, 30) having a detachable distal end that is received within a distal aperture (see, for example, specification page 9, lines 23-26) in the closure component (see, for example, specification page 3, line 16 to page 4, line 9, page 6, lines 3-28, page 7, lines 25-29, page 9, line 14 to page 10, line 24, page 11, line 3 to page 13, line 2, page 13, lines 7-22, page 13, line 28 to page 14, line 2; Figs. 2- 10; reference numerals 28, 50, 70, 80) and extends distal to the distal aperture (see, for example, specification page 9, lines 23-26) when the closure component (see, for example, specification page 3, line 16 to page 4, line 9, page 6, lines 3-28, page 7, lines 25-29, page 9, line 14 to page 10, line 24, page 11, line 3 to page 13, line 2, page 13, lines 7-22, page 13, line 28 to page 14, line 2; Figs. 2-10; reference numerals 28, 50, 70, 80) is in the non-collapsed position, the collapse actuator (see, for example, specification page 5, line 29 to page 6, line 10, page 8, line 11 to page 9, line 26, page 11, line 4 to page 12, line 15, page 13, lines 9-19; Figs. 2-5, 7A, 8; reference numeral 24, 30) being operable to move the collapsible backing (see, for

example, specification page 3, line 19 to page 4, line 11, page 6, lines 13-28, page 7, line 29 to page 8, line 2, page 9, lines 3-14, page 10, lines 24-26, page 11, line 9-11, page 12, line 3 to page 13, line 22, page 14, lines 13-18; Figs. 2-4, 6 ; reference numeral 34, 54, 72) from the non-collapsed position to the collapsed position, and wherein the detachable distal end of the collapse actuator (see, for example, specification page 5, line 29 to page 6, line 10, page 8, line 11 to page 9, line 26, page 11, line 4 to page 12, line 15, page 13, lines 9-19; Figs. 2-5, 7A, 8; reference numeral 24, 30) is configured to assume a deformed profile solely in response to a sufficient proximal force applied to the collapse actuator (see, for example, specification page 5, line 29 to page 6, line 10, page 8, line 11 to page 9, line 26, page 11, line 4 to page 12, line 15, page 13, lines 9-19; Figs. 2-5, 7A, 8; reference numeral 24, 30), the deformed profile permitting the detachable distal end to pass proximally through the distal aperture (see, for example, specification page 9, lines 23-26) and thereby detach from the collapsed closure component (see, for example, specification page 3, line 16 to page 4, line 9, page 6, lines 3-28, page 7, lines 25-29, page 9, line 14 to page 10, line 24, page 11, line 3 to page 13, line 2, page 13, lines 7-22, page 13, line 28 to page 14, line 2; Figs. 2- 10; reference numerals 28, 50, 70, 80).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1-10, 13, 16-21, 23-29, and 31-41 is patentable under 35 U.S.C. 103(a) over Huebsch et al. (U.S. Patent No. 6,312,446) in view of Hart (U.S. Patent No. 5,846,251) and Lafontaine et al. (U.S. Patent No. 5,964,782).

Whether claim 22 is patentable under 35 U.S.C. 103(a) over Huebsch et al. (U.S. Patent No. 6,312,446) in view of Hart (U.S. Patent No. 5,846,251), Lafontaine et al. (U.S. Patent No. 5,964,782), and Luscombe (U.S. Patent No. 5,683,418).

VII. ARGUMENT

A. CLAIMS 1-10, 13, 16-21, 23-29, AND 31-41 ARE PATENTABLE UNDER 35 U.S.C. 103(A) OVER HUEBSCH ET AL. (U.S. PATENT NO. 6,312,446) IN VIEW OF HART (U.S. PATENT NO. 5,846,251) AND LAFONTAINE ET AL. (U.S. PATENT NO. 5,964,782)

1. All words in a claim must be considered in judging the patentability of that claim against the prior art.

The rejections of independent claims 1, 26, and 33 rely largely upon inconsistent interpretations of the shapes found in the configurations assumed by the plugs of Huebsch. The Examiner errs in asserting that the cylindrical configuration in which the plug of Huebsch is delivered has a generally conical shape and that the bipyramidal configuration of the deployed plug teaches a generally disc shaped closure. The plugs of Huebsch have a cylindrical delivery configuration illustrated in Figs. 2 (10) and 14 (200) and which may be seen in Figs. 5a (10'), 5b (10), and 6 (100). The plugs collapse longitudinally with radial expansion to a deployed bipyramid, which may include a space between the bases, illustrated in Figs. 4 and 24 or a dual bipyramid illustrated in Figs. 17 (200)and 22 (200). The configuration is described by Huebsch as assuming its "preform shape in a narrow center portion with enlarged ends" at col. 5, lines 11-12. The deployed device is illustrated in Figs. 5a (10), 5b (10), and 25 (10). Huebsch does not use the descriptive term "cone" or "conical" and the generally conical shape to which the Examiner refers is found only in selected portions of the enlarged ends of the deployed configurations of the plugs of Huebsch. In contrast, the claimed closure device has a non-collapsed generally conical delivery position illustrated in Figs. 2 and 3 (28) and a longitudinally collapsed generally disc shape deployed position as illustrated in Fig. 5 (28), which collapsed position does not involve radial expansion.

In addition, the Examiner consistently assumes that optional tissue anchoring hooks 70 or 27 carried on the struts 22 or 222 as taught by Huebsch may be provided by a "backing" and that said hooks either contact or are capable of contacting an optional coating or covering. No such engaging/entangling contact is disclosed. Hooks 70 or 270

contact or otherwise engage only tissue which lies adjacent to a septal defect. The Examiner often refers to hooks 70 and 270 as associated with plug 200 and then apparently assumes that the optional hooks may instead be associated with an optional coating or covering which may cover the struts 22 or 222 of the device of Huebsch and subsequently turns to Lafontaine to supply a suitable covering material having hooks and pile. As taught at the cited col. 18, lines 24-29, only the interior hooks 370 of inner surface 368 of closure ring 344 of Lafontaine, found in cited Figs. 34A-34C, function to cause the inner surface 368 to engage with itself. The hooks of the inner surface 368 are incapable of engaging tissue on the outside of a ring which might cover a portion of a strut of Huebsch as a replacement for hooks 70 or 270 and thus do not provide fibrous tissue engaging members of the claims. As far as can be determined from the description and the figures of Hart, the ring 344 collapses by flattening to a rectangle in a plane which includes the longitudinal axis of the ring and thus does not collapse to a disc. The Examiner further errs in assuming that replacing the hooks of Huebsch with hooks of Lafontaine will somehow lead one of ordinary skill in the art to relocate the tissue engaging hooks disclosed by Huebsch to a portion to the plug where they would be capable of entangling the backing of which they are a component, but would not be useful for the purpose of engaging tissue. The tissue anchoring members associated with the struts or with the covering must be assumed to be located on portions of the struts of Huebsch which are not taught by Huebsch as having hooks if they are also to entangle a backing pile of Lafontaine. Gaps between the disclosed tips of the optional hooks and the opposed deployed struts of Huebsch are readily apparent in Figs. 22 (270), 24 (70), and 25 (70). Tissue engaging members added to the structures taught by Huebsch in positions which might be capable of contacting an opposed strut surface would serve no apparent purpose in the devices of Huebsch in which hooks serve only to anchor the plug to the tissue surrounding the septal defect. Replacing the hooks taught by Huebsch with the hooks/pile of Lafontaine would not overcome the deficiencies of Huebsch with regard to a plurality of fibrous tissue engaging members which also entangle the backing and which further must assume the recited orientations upon traveling in the proximal and distal directions. One of ordinary skill in the art would not be motivated to replace the tissue hooks of Huebsch with a bioabsorbable pile backing with hooks of Lafontaine "in

order to quickly close the blood vessel" or to further maintain the collapsed configuration of the closure component for the reason that the defect closure capability of the plug of Huebsch is immediately provided by deploying the enlarged ends adjacent to the defect:

> "As shown in FIGS. 4, 5a and 5b, the device will assume a plug like formation when in place, whereby device 10 will span both sides of the septal defect. Device 10 will be anchored to the tissue of the septal defect by the physical interaction such as pressure from struts 22." (col. 4, lines 47-51."

Various internal locking means are disclosed by Huebsch to maintain the plug in its deployed, pressure exerting configuration, thus obviating the need for an alternate means for maintaining a collapsed configuration, particularly when the proposed means appears to be inoperable when positioned in the locations currently taught for the hooks of Huebsch.

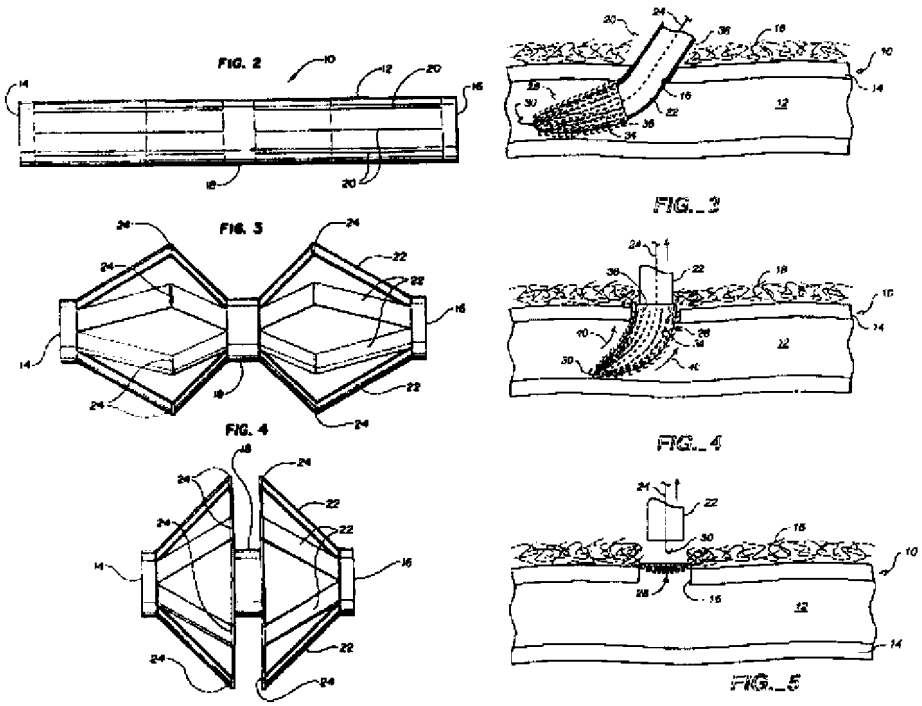
The Examiner errs in characterizing Hart as providing an actuator which overcomes acknowledged deficiencies of the actuator taught by Huebsch. As discussed in the communication of June 3, 2010, the actuator of Hart is not a "collapse actuator" of the pending claims, but rather an expansion actuator. The Examiner errs in the Advisory Action by equating mere deformation of distal end 301 of Hart with collapse. Instead, both element 301 and element 43 assume expanded profiles as a result of the withdrawal of the actuator as shown in Figs. 28E-28H. The actuator of Hart also expands a distal member by pressing against an opposed resisting component of an actuating device in a manner similar to component 230 of the two-part actuators (Figs. 6, 11, and 13) of Huebsch which necessarily collapse the plug both proximally and distally with subsequent engagement of tissue hooks, if present, with opposite sides of the septal tissue trapped therebetween while the single collapse actuator of the pending claims acts upon the conical element which "is configured to assume a deformed profile solely in response to a sufficient proximal force applied to the collapse actuator, the deformed profile permitting the detachable distal end to pass proximally through the distal aperture and thereby detach from the collapsed closure component".

As with the disclosure of Huebsch, the actuators of Hart as depicted in the cited Figs. 4-7 and 28E-28H described at col. 10, lines 28-34 and at col. 13, lines 41-47 require resistance supplied by distal end member 85 of expandable containment member 43 to

expand distal end 301. The discussion of Figs. 28E-28H is somewhat less clear due to the absence of corresponding reference numerals in those figures and the descriptive text. For example, there is no text identifying an element 300 within the disclosure of Hart and no element having that reference numeral in cited Figs. 28E-28H. Other reference numerals are entirely missing from the text or appear to relate to other elements such as guidewire 301 of Figs. 27A-J. Overlooking these inconsistencies, examination of Figs 28A-28H indicates that the proximal end 305 of an element labeled 301 is compressed against distal end 325 of expandable containment member 43 (Figs. 28C-28D) to effect expansion of the element labeled 301 and subsequently expandable containment member 43. As in Huebsch, the action of the combined proximal withdrawal of what appears to be guidewire 310 of the actuator and the opposing force supplied by elements 36/43 serves to expand element 43 and the element labeled 301. Delivered tubular element 43 is expanded radially to a partially inverted deployed double cone structure when the element labeled 301 and/or 312 is withdrawn. Hart does not overcome the deficiencies of Huebsch with regard to a collapse actuator.

The discussion above is believed to provide an adequate basis for requesting that the rejections of all pending claims be overruled. The deficiencies of Huebsch, Lafontaine, and Hart will be discussed in greater detail below should further clarification of the teachings of those references as applied to the current claims be desired.

Both Huebsch and the pending application employ an initially elongated closure component (cylindrical shaft 12, 212 of Huebsch and conical closure device 28 of the pending application) which provides a delivery configuration that is inserted through the opening to be closed. The plug of Huebsch is delivered in a generally cylindrical configuration (Fig. 2, left) while the device of the pending claims is delivered in a generally conical form (Figs. 3 and 4, right) as illustrated below:



Huebsch 10/616,622

The plug of Huebsch, in the deployment configuration of Fig. 2, is inserted approximately halfway through the opening to be plugged while the device of the pending claims is inserted completely through the opening. Once positioned, the plug of Huebsch is collapsed longitudinally from its initially cylindrical delivery configuration to a radially expanded deployed bipyramid which traps the tissue surrounding the septal defect to be closed between the spaced-apart bases of the bipyramids formed by portions of the struts. Accordingly, the device of Huebsch does not teach:

> "a collapsible backing movable between a non-collapsed delivery position, in which the backing has a generally conical shape with a center portion of the backing distally spaced from a periphery of the backing, and a collapsed deployed position, in which the backing center portion is collapsed proximally toward the backing periphery to have a generally disc shape,", as recited in independent claims 1, 26, and 33.

The initially conical device of the pending claims collapses longitudinally to a deployed disc shape within the tissue opening without radial expansion. The initially cylindrical device of Huebsch expands radially to a bipyramidal (or dual bipyramidal)

deployed state. The Examiner is forced to rely upon the deployed state of Fig. 4 to provide both a conical state and the collapsed, deployed state which is then characterized as having instead generally a disc shape. Although the Examiner has characterized the deployed configuration of Huebsch as disc shaped, as illustrated in Fig. 4 above the length of the deployed device, corresponding to the thickness of the supposed disc, is approximately equal to the diameter of the deployed device. The non-flat collapsed bipyramid of Huebsch does not constitute a disc, which is defined as "a flat circular plate". The thin collapsed disc illustrated in Fig. 5 of the pending application (see above) has a diameter approximately five times its thickness and is consistent with the definition of a disc.

The discussion at page 4 of the Final Office Action assumes the presence of a "backing" not present in the figures and asserts that the backing or support 200 of Huebsch is "generally conically shaped and has a center portion 216 distally spaced from the periphery of the backing in the non-collapsed, non-deployed position". The non-collapsed, non-deployed configuration of Huebsch is the cylinder of Fig. 2 above. As seen in Figs. 14-17, which correspond generally to Figs. 2-4 above, reference numeral 216 refers to the distal end of cylindrical shaft 212. Accordingly, the distal end 216 of cylindrical shaft 212 does not appear to provide either a center of catheter delivered device 200 or a center associated with an optional covering for a strut thereof.

Although the Examiner makes reference to a "backing or support" the term "backing" does not appear in Huebsch. The term "support" is used only to refer to support struts 212. Although the Examiner is not bound by the specific word choices employed by Huebsch, "USPTO personnel must always remember to use the perspective of one of ordinary skill in the art." (MPEP 2106) The Examiner's assertion in the Advisory Action that 'a "backing" may considered to be "aid or support of any kind" ... and that the device 200 forms the backing of a septal defect and therefore reads on this limitation' is clearly an erroneous selection of definitions for relevant terms which is at odds with the specification as it would be understood by one of skill in the art. "Where there are several common meanings for a claim term, the patent disclosure serves to point away from the improper meanings and toward the proper meanings."

The Examiner continues by describing only a portion of the deployment process of Huebsch, referring to the retraction of actuator wire 230 without acknowledging that the retraction force thus applied must be countered by a force applied to proximal end 214 by a second actuator component to prevent simple withdrawal of the device without deployment. The Examiner then characterizes the resulting collapse of the putative backing or support 200 to "a collapsed, deployed position in which the center portion is moved proximally toward the backing periphery to form a generally disc shape". Since the putative backing covers the struts of Huebsch, the transformation of the struts from a cylindrical form to a pyramidal (or bipyramidal) form upon longitudinal collapse of either half of the device does not change distances along a strut, said distances lying between the distal end of a strut 222 of cylindrical shaft 212 and the perimeter of the optional strut covering at the hinge point 225 of that strut as illustrated below. The sketch combines portions of Figs. 2 and 4 and the optional tissue hooks of Fig. 24, the presence of said hooks being necessary to provide all elements of the pending claims:

The "center" of the backing or strut 200, indicated by the arrow, does not move toward the "periphery", hinge points 24, as the angular disposition of the strut changes. Similar considerations apply to the fixed length of the portion of the strut between distal end 216 and hinge point 225. Attention is again drawn to the shape transformation taught by Huebsch which is from a delivered cylinder to two, or in some embodiments four, opposed deployed pyramids rather than from a delivery cone shape to a deployed disc shape as recited in the pending claims.

In the Final Office Action, the Examiner errs in asserting that Huebsch teaches a "delivery member which includes a collapsible backing or support 200". Reference numeral 200 of Huebsch is described as:

> "a hollow shaft with cuts or grooves in the wall of the device which create deformable hinged support struts. The shaft may have a circular cross section. The device may suitably be made of any biocompatible material. Alternatively the device could be made of a non-biocompatible material with a suitable biocompatible coating." (Col. 3, lines 51-56.)

The structure and associated optional coating are further described:

> "Cylindrical shaft 212 has parallel struts 222. Struts 222 may be covered by a cloth or other suitable biocompatible covering." (Col. 6, lines 50-52.)

Regardless of the choice of descriptive word, whether cloth or covering or backing, Huebsch does not disclose "a backing" as the term would be understood by one of ordinary skill in the art in view of the pending specification to encompass: "a backing having a generally conical shape"; "a plurality of fibrous tissue engaging members disposed on the backing and oriented in a non-engaging orientation when traveling in a distal direction and in an engaging orientation when traveling in a proximal direction, the fibrous tissue engaging members entangling the backing when the backing is in the collapsed position"; or a backing having "a collapsed deployed position, in which the backing center portion is collapsed proximally toward the backing periphery to have a generally disc shape".

The optional coating or covering which may be applied to the struts of Huebsch do not provide a backing, "something forming a back that is added for strengthening", much less a conical backing capable of entangling hooks. In the Advisory Action, the Examiner has attempted to rely upon the strengthening aspect of a definition of a backing and then to shift focus from the optional covering taught by Huebsch to the entire device 200 of which it is then said "the device 200 forms the backing of a septal defect and therefore reads on this limitation". This interpretation again fails to teach a conical backing having fibrous tissue engaging members, the fibrous tissue engaging members entangling the backing when the backing is in the collapsed configuration. As disclosed by Huebsch, none of tissue anchors 70 or 270 are capable of contacting any remaining portion of device 200 in the fully deployed configuration of the device. This shift in emphasis further weakens the Examiner's position that the ring shaped element 344 of Lafontaine may replace the covering of Huebsch for providing a "strengthening" backing

and thus may provide both engaging hooks and a pile which may be engaged. The asserted ability to engage a pile associated with the backing of Lafontaine assumes that the ring of Lafontaine is positioned in locations other than the locations of the tissue engaging hooks taught by Huebsch. If the device 200 of Huebsch and attached hooks 70 or 270 are now to be considered as providing the backing of Huebsch, then the existing hooks 70 or 270 provide all functions required of the optional hooks of Huebsch and there is no motivation to combine the device of Huebsch with the pile backing 344 of Lafontiane.

In the Advisory Action, the Examiner has asserted "that having the backing of Lafontaine on the exterior surface of Huebsch would still allow the interior hooks to entangle when the backing is collapsed". This presents several difficulties. First and foremost, there are no interior tissue engaging hooks associated with the plug disclosed by Huebsch which might be replaced by the hooks or backing of Lafontaine. Adding hooks to an interior surface of the plug of Huebsch would require a motivation for placing tissue engaging hooks on the plug in a location where there is no possibility that they could engage tissue, since only the exterior of the plug of Huebsch contacts tissue. The Examiner has not supplied a motivation which would lead one of ordinary skill in the art to locate tissue engaging hooks on the interior of the plug where tissue would be inaccessible.

The Examiner also has posited that the backing may be selected to be bioabsorbable in an attempt to provide a motivation for the proposed combination; however if the device 200 of Huebsch is to provide the "backing", absorption of a bioabsorbable device 200 would simply reopen the septal defect which the device is intended to close and one of ordinary skill in the art would not be motivated to make the combination. (Bioabsorption of a tubular element which passes through the defect would simply unplug the defect thereby rendering the plug unsatisfactory for its intended purpose.) Further, it is unclear that the device 200 of Huebsch, if fabricated from the pile backing 344 of Lafontaine, would have sufficient mechanical strength to clamp the device in the septal defect, as required by the principle of operation of Huebsch, and thus it is unclear that one of ordinary skill in the art would be motivated to replace device 200

as taught by Huebsch with a septal defect backing 200 formed from pile backing 344 of Lafontaine as apparently suggested by the Examiner.

If the struts of Huebsch do have an optional cloth or other suitable biocompatible covering; that covering would have the shape of the struts which are at best foldable elongated parallelepipeds and thus the covering of the struts would not be conical in the non-collapsed cylindrical delivery position and further would not be disc-shaped in the collapsed deployed position. As will be seen in Figs. 3, 4, 5a, 5b,6, 8, 9, 14, 16, 17, 21, 22, 23, 24, and 25, there is no backing present between the struts in any illustrated embodiment.

The Examiner has further erred in identifying tissue hooks, variously identified by reference numerals 70 and 270 located near the hinge points 24 or 225, as providing "fibrous tissue engaging members disposed on the backing". Tissue hooks 70 or 270 are illustrated as attached directly to the metal or plastic struts rather than disposed on an intervening backing as recited in the pending claims. The absence of a backing, located where tissue hooks 70 or 270 might engage said backing, is readily apparent in each of Figs. 21, 22, 23, 24, and 25 in which the tissue hooks are present. Further, in those embodiments in which a backing might be present as an optional strut covering, the tissue hooks are clearly positioned such that they are not capable of entangling the backing when the device is in a collapsed position for the reason that they are spaced well apart from any covering which may be associated with an opposing strut in the longitudinally collapsed (radially expanded) position of the devices as may be seen in Figs 22 and 24:

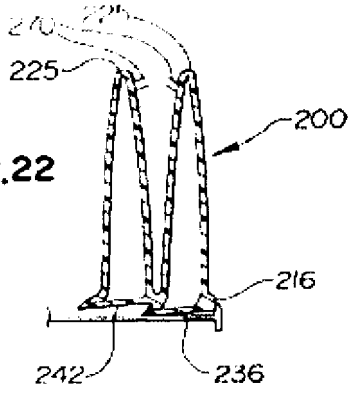
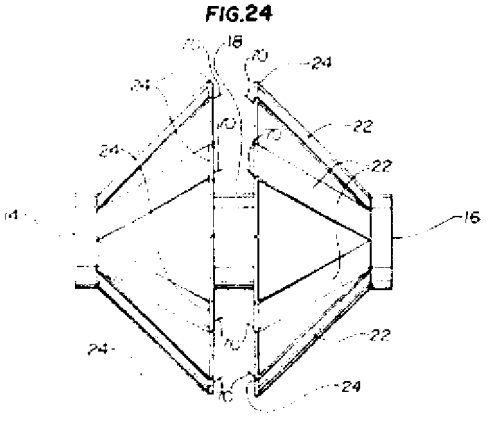


FIG.22

FIG.24

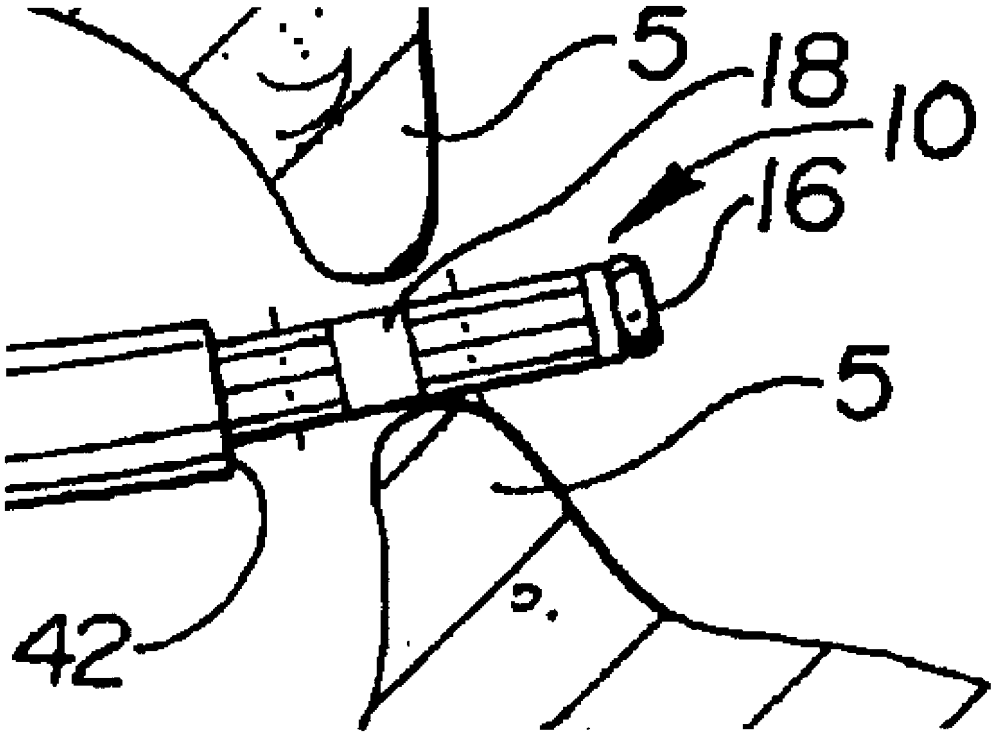


Huebsch does not disclose tissue hooks 70 or 270 along portions of the struts near the centers of the devices where there would be no tissue to engage as seen in the

deployed embodiments illustrated in Figs. 5a, 5b, 22, 24, and 25, but only teaches their presence near the hinge points where there would be intervening tissue with which they may engage to provide "tissue hooks".

The Examiner errs in the Response to Arguments in the Final Office Action by first agreeing that in Huebsch as modified by Lafontaine "the hooks of the pile backing would not engage the pile when collapsed due to the intervening tissue" and then asserting that the hooks would be capable of entangling the backing when "in a collapsed position (as in Figure 17 of Huebsch), without interfering tissue present". Fig. 17 does not include hooks; however the described configuration corresponds to Fig. 22 above in which hooks 270 of Huebsch are illustrated in a collapsed device position without interfering tissue present. Note that the hooks 270 are not positioned to contact the strut upon which they are deployed (except at their points of direct attachment) or the opposed strut. Thus even were one of the pyramidal portions of a deployed structure of Huebsch to be considered in isolation, it does not teach tissue engaging hooks which are capable of engaging a pile covering a strut of that pyramidal configuration. Similarly, as seen in Fig. 24 above, it is not inherent that hooks on one conical portion of a device of Huebsch are capable of contacting a pile, if present, on a second conical portion of the device.

Further still, if the tissue engaging hooks 70 and/or 270 are present in the longitudinally collapsed cylindrical configuration of, for example Fig. 5b of Huebsch, they would not be "oriented in a non-engaging orientation when traveling in a distal direction and in an engaging orientation when traveling in a proximal direction" as may be seen in the modified detail of Fig. 5b presented below. Note that the hooks 270 of cited Fig. 17 (see Fig. 22) are approximately perpendicular to the strut to which they are attached.



(Representations of hooks 70 or 270 added.)

It is apparent above that the addition of tissue engaging hooks having approximately the scale length of elements 70 and 270 to provide tissue engagement would create elements which are not "oriented in a non-engaging orientation when traveling in a distal direction and in an engaging orientation when traveling in a proximal direction" as recited in the claims. Engagement appears to occur readily in either direction since the hooks of Huebsch extend substantially at right angles to the struts where they would directly contact the tissue of the septum as they pass through the opening in the septum. In embodiments of the devices of Huebsch having the deployed form of Fig. 24, some angled hooks 70 face forward and some face backward along the cylinder in the non-deployed state thereby ensuring a tissue engaging orientation when traveling in either the distal or proximal direction.

In discussing Lafontiane, the Examiner notes that the hooks of the claims are not explicitly located upon the exterior surface of the conical collapsible backing. Appellant notes that the plurality of fibrous tissue engaging members are recited as oriented in a tissue engaging orientation when traveling in a proximal direction. As seen in Figs. 3-5, it is only tissue engaging members which are on the outside of the conical backing which are so oriented. Appellant further notes that only one set of fibrous tissue engaging

members is recited in the claims. Accordingly, it is those same fibrous tissue engaging members which must be capable of entangle the backing when the backing is in the collapsed position of Figs. 5, 6, 7A, and 7B. This is not a limitation read into the claim from the specification, but rather a structural feature which results from the respective positions of the tissue and the fibrous tissue engaging members relative to the backing and would be so understood by one of ordinary skill in the art.

Taken as a whole, the tissue engaging hooks of Huebsch, or of Huebsch as modified by Lafontaine, are not positioned to entangle a pile associated with an optional cloth or other suitable biocompatible coating for the struts of Huebsch and do not teach the required orientations of the hooks with respect to travel directions.

With regard to the discussion at page 4 of the Final Office Action, the Examiner characterizes tissue engaging hooks 270 as disposed on a "backing or support 200" and errs in characterizing hooks 270 as proximally facing. As will be seen in Fig. 22, there is no backing upon which the hooks 270 might be disposed and the hooks appear to be approximately perpendicular to the surface of the struts on which they are disposed. To the extent that there may be an angular tilt, the illustrated hooks are distributed between proximal and distal facing orientations on the delivered cylinder and thus do not teach "a plurality of fibrous tissue engaging members disposed on the backing and oriented in a non-engaging orientation when traveling in a distal direction and in an engaging orientation when traveling in a proximal direction". The illustrated operation of the hooks of Huebsch requires that hooks capable of engaging in both directions be present on the tissue facing surfaces of the struts of the plug if, indeed, any hooks are present.

Further, the closure device 200 of Huebsch is not inserted distally <u>through</u> the opening as recited in claim 26, but is inserted into the opening no more than about halfway as may be seen in Figs 5a and 5b. The closure device is not withdrawn proximally relative to the opening as asserted by the Examiner, but rather is <u>symmetrically</u> collapsed both distally and proximally, toward the opening to be closed, by dual actuators 146 and 148. The action is described in the Abstract as:

> "The center of the support struts move radially away from the axis in a hinge like fashion <u>in response to the movement of the device's proximal and distal ends toward the center of the device</u>." (Emphasis added.)

As noted above, the device of Huebsch would simply be withdrawn proximally through the opening by actuator 230 absent an opposing force applied to proximal end 214. Although Huebsch is silent with respect to the means of applying the opposing force, it must be present whether the device collapses sequentially or simultaneously. (Huebsch may suggest a sequential collapse in which the distal portion collapses first. This collapse, if it occurs, necessarily would appear to occur distal of the opening, would result in an enlarged portion of the device disposed distal of the opening, and thus the collapsed distal portion would engage the tissue surrounding the opening thereby preventing expansion/collapse of the portion of the device adjacent proximal end 214 upon further withdrawal of actuator 230. Thus Huebsch, as initially cited by the Examiner, teaches only partial deployment of the device.) In the Advisory Action, the Examiner has acknowledged that the device of Huebsch "necessitates not only a proximal force but also a distal force", but asserts that replacing the non-deformable distal end collapse actuator of Huebsch with the deformable distal end 301 of Hart "will facilitate withdrawal". The issue here is not only the deformable nature of the actuator, but rather that a distal actuator of either Huebsch or Hart will not suffice to deploy the device of Huebsch and will not overcome the deficiencies of Huebsch, or of Huebsch in view of Lafontaine, with regard to a deployable conical backing which is able "to assume a deformed profile solely in response to a sufficient proximal force applied to the collapse actuator". Huebsch teaches that a longitudinal collapse of struts with concurrent radial expansion will cause the device to assume a plug-like formation when in place, whereby device 10 will span both sides of the septal defect. Huebsch does not teach an actuator for a collapsible pile backing and does not teach that a single actuator will suffice. Omission of a required component, the second actuator, is a secondary indicium of nonobviousness.

Further, the actuators of Huebsch are not disclosed as being deformable and their operation indicates that they are substantially rigid in form and operation. The Examiner acknowledged this deficiency of Huebsch and turned to Hart.

The cited col. 10, lines 28-38 of Hart describe relative motions applied to the intermediate slidable obturator sleeve 94 and the fixed obturator sleeve 94 as well as the removal of obturator shaft 72 as necessary to the preferred operation of the embodiment

of cited Figs 4-6. The operation of the alternate embodiment of Figs. 28A-28H has been discussed above with reference directly to the figures since the reference numerals cited in the text at col. 13, lines 41-47 do not appear to correspond to the cited Figs. 28E-28H.

For these reasons and others discussed in greater detail earlier, Huebsch does not disclose the required structural states for delivery and deployment; the expanding actuator of Hart does not overcome the deficiencies of the actuators of Huebsch; and the interior hooks of Lafontaine do not overcome the deficiencies of Huebsch in view of Hart. For at least the reasons discussed above, Huebsch in view of Lafontaine and Hart do not teach all the claim limitations, as is required to establish a *prima facie* case of obviousness nor would one of ordinary skill in the art be motivated to combine the elements of the claims in the manner suggested by the Examiner. Appellant respectfully requests that the rejections of independent claims 1, 26, and 33 be overruled.

2. If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious.

Claims 2-10, 13, 16-21, 23-25, 27-29, 31, 32, and 34-41, which depend from nonobvious independent claims 1, 26, and 33 respectively, also are nonobvious and Appellant respectfully requests that the rejections be overruled.

B. CLAIM 22 IS PATENTABLE UNDER 35 U.S.C. 103(A) OVER HUEBSCH ET AL. (U.S. PATENT NO. 6,312,446) IN VIEW OF HART (U.S. PATENT NO. 5,846,251), LAFONTAINE ET AL. (U.S. PATENT NO. 5,964,782), AND LUSCOMBE (U.S. PATENT NO. 5,683,418).

As discussed above, Huebsch in view of Hart and Lafontaine does not render claim 1 obvious. Luscombe is asserted to provide "the collapse actuator having a frangible connection". A frangible connection is not a limitation of independent claim 1 and so Luscombe does not overcome the deficiencies of Huebsch in view of Hart and Lafontaine as applied to claim 1. Although claim 1 does recite "a collapse actuator releasably coupled to the collapsible backing", the device of Figs 18-20 of Luscombe relies upon resistance applied to anchor 100 through engagement of anchor edge 105 to

create "a rotation of the body of the suture anchor which, in combination with the withdrawal tension, breaks the frangible portion 108 and permits removal of the shaft" as described at col. 7, lines 24-27. Thus the releasable coupling provided by Luscombe does not provide:

> "detachable distal end of the collapse actuator is configured to assume a deformed profile solely in response to a sufficient proximal force applied to the collapse actuator, the deformed profile permitting the detachable distal end to pass proximally through the distal aperture" (Claim 1.)

Luscombe does not overcome the deficiencies of Huebsch in view of Hart and Lafontaine as applied to claim 1. Claim 22, which depends from nonobvious independent claim 1, also is nonobvious and Appellant respectfully requests that the rejection be withdrawn.

C. CONCLUSION

For the reasons stated above, claims 1-10, 13, 16-21, 23-29, and 31-41 are nonobvious over Huebsch in view of Hart and Lafontaine; claim 22 is nonobvious over Huebsch in view of Hart and Lafontaine and further in view of Luscombe; and the Examiner's rejections of claims 1-10, 13, 16-29, and 31-41 under 35 U.S.C § 103 should be overruled.

Respectfully submitted,

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VIII. CLAIMS APPENDIX

1. A closure device for closing an opening in a body cavity, comprising:

an elongate delivery member having a distal end and a proximal end;

a closure component removably connected to the distal end of the delivery member, the closure component including a collapsible backing movable between a non-collapsed delivery position, in which the backing has a generally conical shape with a center portion of the backing distally spaced from a periphery of the backing, and a collapsed deployed position, in which the backing center portion is collapsed proximally toward the backing periphery to have a generally disc shape, and a plurality of fibrous tissue engaging members disposed on the backing and oriented in a non-engaging orientation when traveling in a distal direction and in an engaging orientation when traveling in a proximal direction, the fibrous tissue engaging members entangling the backing when the backing is in the collapsed position; and

a collapse actuator releasably coupled to the collapsible backing, the actuator having a detachable distal end that is received within a distal aperture in the closure component and extends distal to the distal aperture when the closure component is in the non-collapsed position, the collapse actuator being operable to move the collapsible backing from the non-collapsed position to the collapsed position, and wherein the detachable distal end of the collapse actuator is configured to assume a deformed profile solely in response to a sufficient proximal force applied to the collapse actuator, the deformed profile permitting the detachable distal end to pass proximally through the distal aperture and thereby detach from the collapsed closure component.

2. The closure device of claim 1 wherein the backing is formed in a generally elongate conformation, along a generally longitudinal axis of the backing, in the non-collapsed position.

3. The closure device of claim 2 wherein the backing is collapsed generally along the longitudinal axis thereof when in the collapsed position.

4. The closure device of claim 3 wherein the fibrous tissue engaging members form proximally facing hooks.

5. The closure device of claim 4 wherein the proximally facing hooks are spaced along the backing from a proximal portion thereof to a distal portion thereof when the backing is in the non-collapsed position.

6. The closure device of claim 5 wherein the hooks entangle in the backing located proximal of the hooks as the backing moves from the non-collapsed position to the collapsed position.

7. The closure device of claim 4 wherein the body cavity is defined by generally smooth tissue and has fibrous tissue proximal thereof and wherein at least a subset of the plurality of hooks are oriented to engage the fibrous tissue as the hooks travel in a proximal direction relative to the fibrous tissue.

8. The closure device of claim 7 wherein the closure component has a first row of hooks disposed about the backing periphery.

9. The closure device of claim 8 wherein the first row of hooks passes along the generally smooth tissue without engaging the generally smooth tissue and engages the fibrous tissue as the closure component is moved proximally relative thereto.

10. The closure device of claim 4 wherein the closure component has a first row of hooks disposed about a proximal end thereof and wherein the first row of hooks includes tissue piercing hooks that pierce tissue as they are moved proximally relative thereto.

11. The closure device of claim 4 wherein the backing comprises a resilient web stretched over a distal support structure on the elongate delivery member.

12. The closure device of claim 4 wherein the backing forms a cone with collapsible rings, spaced from one another along the longitudinal axis thereof when in the non-collapsed position and generally collapsed relative to one another along the longitudinal axis thereof when in the collapsed position.

13. The closure device of claim 1 and further comprising:

an active actuator having a distal engaging end disconnectably connecting the closure component to the delivery member and a proximal end receiving an actuation input and actuating the distal engaging end to release the closure component in response to the actuation input.

14. The closure device of claim 1 wherein the backing generally forms a web having collapsible support members supporting the web in the non-collapsed position.

15. (Canceled).

16. The closure device of claim 1 wherein the detachable distal end of the collapse actuator is releasably coupled to a distal end of the closure component and is configured to move the distal end of the closure component under proximally directed force applied to the elongate member.

17. The closure device of claim 16 in which the detachable distal end of the collapse actuator includes a deformable hook for releasably coupling the collapse actuator to the closure component.

18. The closure device of claim 17 wherein the deformable hook is located distal of the distal aperture when the closure component is in the non-collapsed position.

19. The closure device of claim 18 wherein the deformable hook moves from a distal end of the closure component to a more proximal position to collapse the closure component under proximally directed force applied to the collapse actuator.

20. The closure device of claim 19 wherein the deformable hook deforms to pass through the distal aperture in the closure component after the closure component has moved to the collapsed position under continued application of proximally directed force on the collapse actuator.

21. The closure device of claim 16 wherein the collapse actuator comprises a wire.

22. The closure device of claim 21 wherein the wire comprises a frangible connection to the distal end of the closure component.

23. The closure device of claim 21 wherein the wire comprises a mechanically releasable connection to the distal end of the closure component.

24. The closure device of claim 1 wherein the closure component is formed of a biocompatible material.

25. The closure device of claim 1 wherein the closure component is formed of a bioabsorbable material.

26. A method of closing an opening in a body, comprising:

inserting distally through the opening a closure component having collapsible pile backing with pile engaging hooks and tissue engaging hooks disposed thereon, the pile backing initially have a non-collapsed delivery position in which the backing has a generally conical shape with a center portion of the backing distally spaced from a periphery of the backing;

withdrawing the closure component proximally relative to the opening such that the tissue engaging hooks engage tissue adjacent the opening;

applying proximally directed force to a collapse actuator releasably coupled to the collapsible pile backing and having a detachable distal end received within a distal

aperture of the collapsible pile backing, the detachable distal end extending distal to the distal aperture, thereby to collapse the collapsible pile backing to a collapsed position in which the backing center portion is moved proximally toward the backing periphery to form a generally disc shape, and wherein the pile engaging hooks engage portions of the pile backing to retain the pile backing in the collapsed position; and

disconnecting the collapse actuator from the collapsible pile backing by applying additional proximally directed force on the collapse actuator, thereby causing the detachable distal end of the collapse actuator to assume a deformed profile solely in response to a sufficient proximal force applied to the collapse actuator, the deformed profile permitting the detachable distal end to pass proximally through the distal aperture and the collapsed pile backing.

27. The method of claim 26 wherein inserting comprises:

inserting the closure component with an elongate delivery member, the closure component being disposed at a distal end of the delivery member.

28. The method of claim 27 and further comprising:

disconnecting the closure component from the distal end of the delivery member.

29. The method of claim 28 wherein disconnecting comprises:

exerting proximally directed force on the delivery member after collapsing the collapsible pile.

30. (Canceled)

31. The method of claim 26 wherein the tissue engaging hooks are comprised of tissue piercing hooks that pierce the tissue when the tissue is engaged.

32. The method of claim 26 wherein the opening is in a body cavity defined by media and having adventitia adjacent thereto and wherein withdrawing comprises:

withdrawing the tissue engaging hooks proximally past the media to engage the adventitia.

33. A closure device for closing an opening in a body cavity, comprising:

an elongate delivery member having a distal end and a proximal end;

an implantable closure component disconnectably connected to the distal end of the delivery member, the closure component including a longitudinally collapsible backing movable between a non-collapsed delivery position, in which the backing has a generally conical shape with a center portion of the backing distally spaced from a periphery of the backing, and a collapsed deployed position, in which the backing center portion is collapsed proximally toward the backing periphery to have a generally disc shape, and a plurality of fibrous tissue engaging members on the backing and engaging the backing when the backing is in the collapsed position; and

a collapse actuator releasably coupled to the collapsible backing, the actuator having a detachable distal end that is received within a distal aperture in the closure component and extends distal to the distal aperture when the closure component is in the non-collapsed position, the collapse actuator being operable to move the collapsible backing from the non-collapsed position to the collapsed position, and wherein the detachable distal end of the collapse actuator is configured to assume a deformed profile solely in response to a sufficient proximal force applied to the collapse actuator, the deformed profile permitting the detachable distal end to pass proximally through the distal aperture and thereby detach from the collapsed closure component.

34. The closure device of claim 33 wherein the fibrous tissue engaging members are oriented in a non-engaging orientation when traveling in a distal direction and in an engaging orientation when traveling in a proximal direction.

35. The closure device of claim 33 wherein the backing is formed in a generally elongate conformation, along a generally longitudinal axis of the backing, in the non-collapsed position.

36. The closure device of claim 33 wherein the fibrous tissue engaging members form proximally facing hooks.

37. The closure device of claim 36 wherein the proximally facing hooks are spaced along the backing from a proximal portion thereof to a distal portion thereof when the backing is in the non-collapsed position.

38. The closure device of claim 37 wherein the hooks entangle in the backing located proximal of the hooks as the backing moves from the non-collapsed position to the collapsed position.

39. The closure device of claim 38 wherein the body cavity is defined by generally smooth tissue and has fibrous tissue proximal thereof and wherein at least a subset of the plurality of hooks are oriented to engage the fibrous tissue as the hooks travel in a proximal direction relative to the fibrous tissue.

40. The closure device of claim 1 wherein the fibrous tissue engaging members and the backing are disposed on a same surface of the closure component.

41. The closure device of claim 40 wherein the same surface comprises an exterior surface of the closure component.

IX. EVIDENCE APPENDIX

No additional evidence has been presented.

X. RELATED PROCEEDINGS APPENDIX

None.